

A. Rejections Under 35 U.S.C. § 112.

Based upon the Examiner's comments, it appears that the expressions objected to are, in fact, perfectly understood, since the Examiner has been able to formulate a detailed rejection under 35 U.S.C. § 103 and respond to Applicant's arguments traversing same, but the Examiner is objecting to the breadth of the claimed terms. As a matter of law a rejection based upon breadth of the claim is improper and must be removed. In re Miller, 169 USPQ 597 (CCPA 1971) (Breadth of a claim is not to be equated with indefiniteness.)

Moreover, one skilled in the art readily understands what the terms to which the Examiner objects, i.e., "would," "beneficial effect," "slowly enough," "actives" and "temperature capable of denaturing the active," mean – especially given the definitions in the specification, and the Examiner has provided no objective evidence to the contrary. See Andrew Corp. v. Gabriel Electronics, 6 USPQ2d 2010 (Fed. Cir. 1988) (The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal.") (emphasis added). First, the Examiner objects to the use of the word "would" in the claims. "Would" is a common English word that should be given its common English meaning. Specifically, as made plain by the teachings of the specification, the invention involves, inter alia, adding an active to a composition at a temperature at which the active would normally be denatured. There is nothing indefinite about the use of "would."

The Examiner's comments regarding the definition of "beneficial effect," namely "a measurable desired change..." are simply not understood. Different actives yield different beneficial effects and those can be measured, which is how the presence or effectiveness of the active is often determined. These are common English words and expressions, are used by persons skilled in this art, and the Examiner has not explained why persons skilled in the art would not understand them. The Examiner further asserts that she cannot understand the term "active" because the specification does not explain what may be considered a "biologically active substance." Yet, the specification itself plainly states that actives include "enzymes, antibodies, vitamins or a combination thereof." Application, p. 1, ll. 11-13.

The Examiner's comments with respect to the term "slowly enough" are also not understood especially considering that the term "denatured" is a standard English word readily understood by those skilled in the art. Relative claims terms such as "slowly" are frequently

used in patent claims (especially in the chemical arts), and are definite as long as persons skilled in the art would understand the meets and bounds of the invention. In re Moore, 169 USPQ 236, 238 (CCPA 1971) ("[T]he definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art."); Seattle Box Co., v. Industrial Crating & Packing, Inc., 221 USPQ 568 (Fed. Cir. 1984); MPEP § 2173.05 (b) (Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.) Here, the Examiner has again provided no objective evidence as to why persons skilled in the art would not understand the phrase "slowly enough" as used in the claims.

The same holds true for the Examiner's position regarding the expression "the temperature that would denature the active." The temperature depends on the active used and such temperatures are known to those skilled in the art or are readily ascertainable without undue experimentation and the Examiner has provided no objective evidence whatsoever to support this rejection. "Denature" is a common expression known to those in the art and it means to render the active inactive. The Examiner's comment about "requisite degree" is not explained, is not understood and is irrelevant. Furthermore, using such rationale, apparently nothing would be definite since even the accepted boiling point of water depends on numerous factors, such as pressure and impurities in the water. Using another example, the term "agitated" would apparently be indefinite using such reasoning since it does not explain the speed or thoroughness of the agitation, hence the "degree" of agitation would be unknown. In this case, the claim language means what it says – denatured means that the active is made inactive, which means that it does not render a measurable beneficial effect.

In addition to the case law and MPEP rules supporting Applicant's claim language, Applicant submits hereto Exhibit 1, which includes a list of U.S. patents issued since 1990 that include the term "beneficial" in the claims. 600 issued U.S. patents were located, 192 of which are in the same art class as this Application. Also included in Exhibit 1 are representative patents from this list – NONE of the representative patents (according to the USPTO search software) even include the term "beneficial" in the specification; thus no definition of the term "beneficial" was provided. Attached as part of Exhibit 2 is a list of U.S. patents issued since 1990 that include the term "slowly" in the claims. 2,932 issued U.S. patents were located, 197 of which

are in the same art class as this Application. Also included in Exhibit 2 are representative patents from this list – NONE of the representative patents (according to the USPTO search software) even include the term “slowly” in the specification, thus no definition of the term “slowly” was provided. This is strong evidence that such words are commonly used in chemical patents, are understood by those skilled in the art and are definite.

If the Examiner persists in maintaining these rejections after considering the evidence and arguments herein, Applicant respectfully requests that the Examiner present objective evidence to support the rejection.

B. Rejections Under 35 U.S.C. §103.

Applicant respectfully submits that the continued rejection under 35 U.S.C. § 103 reflects a misunderstanding of the invention or perhaps a misunderstanding of Monte ‘843. The invention allows for, among other things, the addition of an active to a substance while the substance is at a temperature that would normally denature the active and, utilizing the invention, the active is not denatured. As explained in the Background and Summary of the Invention sections, this is a significant improvement over the prior art and the Examiner’s continued reliance on Monte ‘843 is misplaced because it does not teach, suggest or show this feature. (Applicant again notes that Monte is the inventor of the present application and thoroughly understands the difference between this invention and his prior inventions.) The specific sections of Monte ‘843 cited by the Examiner are addressed below:

1. The abstract does not even address the temperature at which an active is added to a composition.
2. Column 1, lines 21-39 merely describe a prior art method and the deficiencies thereof. 140 degrees F is below the denaturing temperature of lactase enzyme. The same prior art example is recited on page 4, lines 14-23 of the present application.
3. Column 2, lines 7-10 appear to have nothing to do with the temperature at which the active is added to the composition.
4. Nothing in claims 4 or 5 teaches, suggests or shows that an active is added to the composition at or above the denaturing temperature.

In view of the comments above, Applicant submits that the rejection under 35 U.S.C. § 103 is traversed.

III. Conclusion.

In view of the amendments and arguments herein, this Application is believed to be in condition for allowance and favorable action is requested. Applicant reserves the right to prosecute additional claims, including claims of broader scope, in a continuation application.

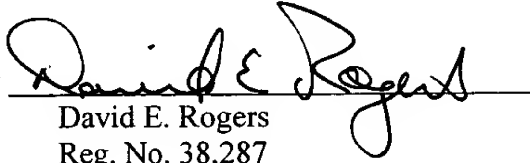
The Examiner is invited to telephone the undersigned at the telephone number listed below if it would in any way advance prosecution of this case.

Respectfully submitted,

7-28-03

Date

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